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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,597	06/26/2003	Mark L. Faupel	SPRX-023USC1	2992

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EXAMINER	
DAHBOUR, FADI H	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,597	FAUPEL ET AL.	
	Examiner	Art Unit	
	Fadi H. Dahbour	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,11,17-23,27,28 and 34-37* is/are rejected.

7)☒ Claim(s) *7-9,12-16,24-26 and 29-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 10-11, 17-18, 19-23, 27-28, 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Benaron et al (US5762609).

Regarding claims 1-6, 10-11, 17-18, 36, Benaron discloses a method for diagnosing a condition of a target tissue (Figs.1-9), comprising irradiating a target tissue with excitation electromagnetic radiation (see "radiative" & "energy emitted into the tissue" in lines 24, 26-27 of col.5), sensing a returned electromagnetic radiation returned from the target tissue (see "detection of radiative energy" in lines 23-24 of col.5), determining characteristics of the returned electromagnetic radiation using at least two spectroscopic methods (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), combining the

characteristics determined by the at least two spectroscopic methods, thereby decoupling biochemical changes from morphological changes in the target tissue (see "chemical and histological change within the tissue" in lines 46-47 of col.8, also see "chemical and/or histological changes" in line 51 of col.9), determining a condition of the target tissue based on the combined determined characteristics (see "to assess the status of tissue during a surgical intervention" in lines 40-41 of col.7), wherein the at least two spectroscopic methods comprise fluorescence measurements and scattering or reflectance measurements (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), wherein the at least two spectroscopic methods are selected from the group consisting of absorption measurements, scattering measurements, reflection measurements, polarization anisotropic measurements, steady state fluorescence measurements, and time resolved fluorescence measurements (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), wherein the time resolved fluorescence measurements comprise at least one of phase modulation techniques, polarization anisotropic techniques and techniques that directly monitor the decay profile of fluorescent emissions (see "techniques such as phase-shift" in lines 7-8 of col.6), simultaneously sensing electromagnetic radiation emitted from the target tissue in response to the excitation electromagnetic radiation and excitation electromagnetic radiation that is scattered from the target tissue (see "the detectors are preferably configured to be sensitive to the detection of radiative energy reaching the detector by a route that is selected from one or more of transmission, reflection,

scattering, fluorescence, and remission" in lines 22-26 of col.5), and making intensity based measurements on both the electromagnetic radiation emitted from the target tissue in response to the excitation electromagnetic radiation and the excitation electromagnetic radiation that is scattered from the target tissue (see "a controller to operate selectively the more than one...detector to produce a plurality of measures of radioactive energy corresponding to emitted radiation..." in lines 56-59 of col.22), sensing electromagnetic radiation returned from a plurality of interrogation points distributed over the target tissue (see "a plurality of...detector... spaced along a tissue" in lines 44-45 of col.15), further comprising a step of dividing the target tissue into a first set of field areas (see "a plurality of portions of tissue" in line 16 of col.20) and determining characteristics of the returned electromagnetic radiation in each of the first set of field areas using at least two spectroscopic methods (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5, also see "a plurality of portions of tissue" in line 16 of col.20) and combining the characteristics determined by the at least two spectroscopic methods for each of the first set of field areas (see "chemical and histological change within the tissue" in lines 46-47 of col.8, also see "chemical and/or histological changes" in line 51 of col.9, also see "a plurality of portions of tissue" in line 16 of col.20), and determining a condition of the target tissue by comparing the combined determined characteristics of each of the first set of field areas (see "comparing repeated measures of detected radiative energy over time, said repeated measures being selected to provide a measure of...tissue status" in lines 9-11 of col.22, also see "a plurality of portions of tissue representing the

status of the tissue portions" in lines 16-17 of col.20), generating a map of conditions of different portions of the target tissue based on the combined determined characteristics (see "forming an image of said portions" in line 29 of col.22), further comprising a step of conducting a pattern recognition process to determine whether a pattern of conditions exists within the target tissue (see "comparing repeated measures" in line 9 of col.22).

Regarding claims 19-23, 27-28, 34-35, 37, Benaron discloses a system for determining a condition of a target tissue in a human or animal (Figs.1-9), comprising an electromagnetic radiation source for providing excitation electromagnetic radiation (see "radiative" & "energy emitted into the tissue" in lines 24, 26-27 of col.5), a device that couples the excitation electromagnetic radiation to a target tissue (see "grasper means arranged to hold the tissue proximately coupled to the light emitter" in lines 45-47 of col.6), a device that senses a returned electromagnetic radiation returned from the target tissue (see "detectors...detection of radiative energy" in lines 22-24 of col.5), a processor (see "processor" in line 11 of col.19) configured for determining characteristics of the returned electromagnetic radiation using at least two spectroscopic methods (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), combining the characteristics determined by the at least two spectroscopic methods, thereby decoupling biochemical changes from morphological changes in the target tissue (see "chemical and histological change within the tissue" in lines 46-47 of col.8, also see "chemical and/or histological changes" in line 51 of col.9), determining a condition of the target tissue based on the combined determined characteristics (see "to assess the

status of tissue during a surgical intervention" in lines 40-41 of col.7), wherein the at least two spectroscopic methods comprise fluorescence measurements and scattering or reflectance measurements (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), wherein the at least two spectroscopic methods are selected from the group consisting of absorption measurements, scattering measurements, reflection measurements, polarization anisotropic measurements, steady state fluorescence measurements, and time resolved fluorescence measurements (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5), the device that senses returned electromagnetic radiation is configured for simultaneously sensing fluorescent radiation emitted by endogenous fluorophores in response to the excitation radiation and excitation electromagnetic radiation that is scattered from the target tissue (see "the detectors are preferably configured to be sensitive to the detection of radiative energy reaching the detector by a route that is selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 22-26 of col.5), wherein the processor (see "processor" in line 11 of col.19) makes intensity based measurements on both the fluorescent radiation emitted by endogenous fluorophores from in response to the excitation radiation and the excitation electromagnetic radiation that is scattered from the target tissue (see "a controller to operate selectively the more than one...detector to produce a plurality of measures of radioactive energy corresponding to emitted radiation..." in lines 56-59 of col.22), the device that senses electromagnetic radiation is configured for sensing electromagnetic radiation returned from a plurality of

interrogation points distributed over the target tissue (see "a plurality of...detector... spaced along a tissue" in lines 44-45 of col.15), wherein the processor (see "processor" in line 11 of col.19) divides the target tissue into a first set of field areas (see "a plurality of portions of tissue" in line 16 of col.20) and determines characteristics of the returned electromagnetic radiation in each of the first set of field areas using at least two spectroscopic methods (see "selected from one or more of transmission, reflection, scattering, fluorescence, and remission" in lines 25-26 of col.5, also see "a plurality of portions of tissue" in line 16 of col.20) and combines the characteristics determined by the at least two spectroscopic methods for each of the first set of field areas (see "chemical and histological change within the tissue" in lines 46-47 of col.8, also see "chemical and/or histological changes" in line 51 of col.9, also see "a plurality of portions of tissue" in line 16 of col.20), and determines a condition of the target tissue in each of the first set of field areas based on the combined determined characteristics of the respective field areas (see "comparing repeated measures of detected radiative energy over time, said repeated measures being selected to provide a measure of...tissue status" in lines 9-11 of col.22, also see "a plurality of portions of tissue representing the status of the tissue portions" in lines 16-17 of col.20), wherein the processor (see "processor" in line 11 of col.19) is configured to create a map of determined conditions of different portions of the target tissue (see "forming an image of said portions" in line 29 of col.22), wherein the processor (see "processor" in line 11 of col.19) is configured to conduct a pattern recognition process to determine whether a pattern of conditions exists within the target tissue (see "comparing repeated measures" in line 9 of col.22).

Allowable Subject Matter

2. Claims 7-9, 12-16, 24-26, 29-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fadi H. Dahbour whose telephone number is 703-306-5479. The examiner can normally be reached on M-F, 9am-5:30pm est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fadi H. Dahbour
Examiner
Art Unit 3743